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- and -

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IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

CAROL J. STRONG,

X

Plaintiff,

ν.

NOVARTIS PHARMACEUTICALS CORPORATION, MERCK & CO., INC., PROCTER & GAMBLE PHARMACEUTICALS, INC. AND AVENTIS PHARMACEUTICALS, INC.,

Defendants.

CIVIL ACTION NO. 1:8-CV-4100

ANSWER

Procter & Gamble Pharmaceuticals, Inc. ("P&G") and sanofi-aventis U.S. L.L.C. ("sanofi-aventis US"), successor in interest to Aventis Pharmaceuticals, Inc., answer Plaintiff Carol J. Strong's ("Plaintiff") Original Complaint ("Complaint") as follows:

1. In answer to paragraph 1 of the Complaint, P&G and sanofi-aventis US admit that this is a civil action for alleged damages suffered by Plaintiff Carol J. Strong. However, P&G

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and sanofi-aventis US deny that Plaintiff suffered any damages as a result of her allegedly being prescribed and her alleged ingestion of the medication Actonel.

PARTIES

- 2. In answer to paragraph 2 of the Complaint, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 3. The allegations in paragraph 3 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 4. The allegations in paragraph 4 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 5. In answer to paragraph 5 of the Complaint, Defendant P&G admits that it is an Ohio corporation with its principal place of business in Cincinnati, Ohio. Defendant P&G denies any remaining allegations.
- 6. In answer to paragraph 6 of the Complaint, Defendant sanofi-aventis US admits that it is a Delaware corporation with its principal place of business in New Jersey. Defendant sanofi-aventis US denies any remaining allegations.

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7. In answer to paragraph 7 of the Complaint, P&G and sanofi-aventis US admit that they conduct business in the State of New York. Defendant P&G denies that it conducts business in the State of Montana. Defendant sanofi-aventis US admits that it conducts business in the State of Montana. P&G and sanofi-aventis US deny any remaining allegations.

JURISDICTION

8. In answer to paragraph 8 of the Complaint, P&G and sanofi-aventis US admit that jurisdiction is proper in federal court. P&G and sanofi-aventis US further admit that Plaintiff, upon information and belief, and P&G and sanofi-aventis US, are citizens of different states. Although they deny Plaintiff is entitled to any damages whatsoever pertaining to Plaintiff's alleged injuries, P&G and sanofi-aventis US admit that, upon information and belief, the amount in controversy appears to be greater than \$75,000.

FACTUAL BACKGROUND

- 9. The allegations in paragraph 9 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 10. The allegations in paragraph 10 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

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- 11. The allegations in paragraph 11 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 12. The allegations in paragraph 12 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 13. The allegations in paragraph 13 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 14. The allegations in paragraph 14 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 15. The allegations in paragraph 15 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief

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as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

- 16. The allegations in paragraph 16 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 17. The allegations in paragraph 17 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 18. The allegations in paragraph 18 of the Complaint, including all sub-parts, are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 19. The allegations in paragraph 19 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

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20. The allegations in paragraph 20 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

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- 21. The allegations in paragraph 21 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 22. The allegations in paragraph 22 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 23. The allegations in paragraph 23 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 24. The allegations in paragraph 24 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief

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as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

- 25. The allegations in paragraph 25 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 26. The allegations in paragraph 26 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 27. The allegations in paragraph 27 of the Complaint, including all sub-parts, are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 28. In answer to paragraph 28 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US denies the remaining allegations contained in paragraph 28.

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- 29. In answer to paragraph 29 of the Complaint, P&G and sanofi-aventis US admit that Actonel is a brand name of risedronate sodium and that it is a prescription bisphosphonate that is taken orally. P&G and sanofi-aventis US deny any remaining allegations.
- 30. In answer to paragraph 30 of the Complaint, P&G and sanofi-aventis US admit that Actonel was approved by the United States Food and Drug Administration ("FDA") for prevention and treatment of osteoporosis.
- 31. In answer to paragraph 31 of the Complaint, P&G and sanofi-aventis US deny the allegations. By way of further answer, P&G and sanofi-aventis US state that the Actonel labeling and package inserts were approved by FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.
 - 32. P&G and sanofi-aventis US deny the allegations contained in paragraph 32.
- 33. In answer to paragraph 33 of the Complaint, P&G and sanofi-aventis US deny the allegations. By way of further answer, P&G and sanofi-aventis US state that the Actonel labeling and package inserts were approved by FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.
- 34. In answer to paragraph 34 of the Complaint, P&G and sanofi-aventis US state that they lack knowledge and information sufficient to form a belief regarding the truth or falsity of the allegations, and therefore deny the allegations contained therein.
 - 35. P&G and sanofi-aventis US deny the allegations contained in paragraph 35.
- 36. P&G and sanofi-aventis US deny the allegations contained in paragraph 36, including all separate subparts.

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FIRST CLAIM FOR RELIEF

[Strict Product Liability - Design Defect]

- 37. P&G and sanofi-aventis US incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 36 above.
- 38. The allegations in paragraph 38 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 39. The allegations in paragraph 39 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 40. The allegations in paragraph 40 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 41. The allegations in paragraph 41 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief

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as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

- The allegations in paragraph 42 of the Complaint are not directed to P&G and 42. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- The allegations in paragraph 43 of the Complaint are not directed to P&G and 43. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 44. The allegations in paragraph 44 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- The allegations in paragraph 45 of the Complaint are not directed to P&G and 45. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

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- The allegations in paragraph 46 of the Complaint are not directed to P&G and 46. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- The allegations in paragraph 47 of the Complaint are not directed to P&G and 47. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- The allegations in paragraph 48 of the Complaint are not directed to P&G and 48. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- The allegations in paragraph 49 of the Complaint are not directed to P&G and 49. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- In answer to paragraph 50 of the Complaint, Defendant P&G admits that it 50. designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US admits that it marketed, distributed and sold Actonel

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in the United States. Defendant sanofi-aventis US denies the remaining allegations contained in paragraph 50.

- 51. P&G and sanofi-aventis US deny the allegations contained in paragraph 51.
- 52. P&G and sanofi-aventis US deny the allegations contained in paragraph 52.
- 53. P&G and sanofi-aventis US deny the allegations contained in paragraph 53.
- 54. P&G and sanofi-aventis US deny the allegations contained in paragraph 54.
- 55. P&G and sanofi-aventis US deny the allegations contained in paragraph 55.

SECOND CLAIM FOR RELIEF

[Strict Product Liability - Failure to Warn]

- 56. P&G and sanofi-aventis US incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 36 above.
- 57. The allegations in paragraph 57 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 58. The allegations in paragraph 58 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 59. The allegations in paragraph 59 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is

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required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

- 60. The allegations in paragraph 60 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 61. The allegations in paragraph 61 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 62. The allegations in paragraph 62 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 63. The allegations in paragraph 63 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

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- The allegations in paragraph 64 of the Complaint are not directed to P&G and 64. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- In answer to paragraph 65 of the Complaint, Defendant P&G admits that it 65. designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US denies the remaining allegations contained in paragraph 65.
 - P&G and sanofi-aventis US deny the allegations contained in paragraph 66. 66.
 - 67. P&G and sanofi-aventis US deny the allegations contained in paragraph 67.
 - P&G and sanofi-aventis US deny the allegations contained in paragraph 68. 68.

THIRD CLAIM FOR RELIEF

[Negligence]

- 69. P&G and sanofi-aventis US incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 36 above.
- The allegations in paragraph 70 of the Complaint are not directed to P&G and 70. sanofi-aventis US and therefore require no response from them. To the extent a response is required. P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

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- The allegations in paragraph 71 of the Complaint are not directed to P&G and 71. sanofi-aventis US therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 72. The allegations in paragraph 72 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- The allegations in paragraph 73 of the Complaint are not directed to P&G and 73. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- The allegations in paragraph 74 of the Complaint are not directed to P&G and 74. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 75. The allegations in paragraph 75 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief

ANSWER -15as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

- 76. The allegations in paragraph 76 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 77. The allegations in paragraph 77 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 78. The allegations in paragraph 78 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 79. The allegations in paragraph 79 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

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- In answer to paragraph 80 of the Complaint, Defendant P&G admits that it 80. designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis US denies the remaining allegations contained in paragraph 80.
- In answer to paragraph 81 of the Complaint, P&G and sanofi-aventis US admit 81. that they had a duty to comply with all applicable law, which they did. P&G and sanofi-aventis US deny the remaining allegations contained in paragraph 81.
 - P&G and sanofi-aventis US deny the allegations contained in paragraph 82. 82.
 - P&G and sanofi-aventis US deny the allegations contained in paragraph 83. 83.

FOURTH CLAIM FOR RELIEF

[Breach of Express Warranty]

- 84. P&G and sanofi-aventis US incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1, through 36 above.
- The allegations in paragraph 85 of the Complaint are not directed to P&G and 85. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- The allegations in paragraph 86 of the Complaint are not directed to P&G and 86. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief

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as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

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- 87. The allegations in paragraph 87 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 88. The allegations in paragraph 88 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 89. The allegations in paragraph 89 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 90. The allegations in paragraph 90 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

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- The allegations in paragraph 91 of the Complaint are not directed to P&G and 91. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 92. The allegations in paragraph 92 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
 - P&G and sanofi-aventis US deny the allegations contained in paragraph 93. 93.
- In answer to paragraph 94 of the Complaint, P&G and sanofi-aventis US lack 94. knowledge and information sufficient to form a belief regarding the truth or falsity of the allegations asserted, and therefore deny the allegations contained therein.
 - 95. P&G and sanofi-aventis US deny the allegations contained in paragraph 95.
 - 96. P&G and sanofi-aventis US deny the allegations contained in paragraph 96.

FIFTH CLAIM FOR RELIEF

[Breach of Implied Warranty]

- 97. P&G and sanofi-aventis US incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 36 above.
- The allegations in paragraph 98 of the Complaint are not directed to P&G and 98. sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief

ANSWER -19as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

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- 99. The allegations in paragraph 99 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 100. The allegations in paragraph 100 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 101. The allegations in paragraph 101 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 102. The allegations in paragraph 102 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

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- 103. The allegations in paragraph 103 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 104. The allegations in paragraph 104 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
- 105. The allegations in paragraph 105 of the Complaint are not directed to P&G and sanofi-aventis US and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.
 - 106. P&G and sanofi-aventis US deny the allegations contained in paragraph 106.
- 107. In answer to paragraph 107 of the Complaint, P&G and sanofi-aventis US lack knowledge and information sufficient to form a belief regarding the truth or falsity of the allegations asserted, and therefore deny the allegations contained therein.
 - 108. P&G and sanofi-aventis US deny the allegations contained in paragraph 108.
 - 109. P&G and sanofi-aventis US deny the allegations contained in paragraph 109.

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PRAYER FOR RELIEF

110. Plaintiff's "Prayer for Relief" section of the Complaint does not contain allegations of fact and therefore no responsive pleading is required. To the extent a response is deemed necessary, P&G and sanofi-aventis US deny each and every allegation and assertion listed under the "Prayer for Relief" section of Plaintiff's Complaint and deny that Plaintiff is entitled to any of the relief requested.

AFFIRMATIVE DEFENSES

111. Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable P&G and sanofi-aventis US to determine all, of their legal, contractual and equitable rights, P&G and sanofi-aventis US hereby give notice that they intend to rely upon such other defenses as may become available or appear during discovery proceedings in this case and hereby reserve the right to amend and/or supplement this answer to assert any such defense at a future time and in conformity with the Federal Rules of Civil Procedure.

FIRST AFFIRMATIVE DEFENSE

112. The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

113. Any product for which P&G and sanofi-aventis US were responsible at the time of the occurrences or injuries allegedly suffered by Plaintiff was not defective and unreasonably dangerous in its design, manufacture, or marketing, and it was at all times reasonably safe and reasonably fit for its intended use. The warnings and instructions accompanying the product at issue in this case were legally adequate warnings and instructions.

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THIRD AFFIRMATIVE DEFENSE

114. Plaintiff's claims are barred in whole or in part because P&G and sanofi-aventis US provided adequate "direction or warnings" as to the use of any of its products within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

FOURTH AFFIRMATIVE DEFENSE

115. P&G and sanofi-aventis US assert the applicability of comment k of the Restatement (Second) of Torts § 402A, which bars Plaintiff's claims in this lawsuit.

FIFTH AFFIRMATIVE DEFENSE

116. P&G and sanofi-aventis US deny that Plaintiff used any product manufactured or marketed by P&G and sanofi-aventis US as alleged in Plaintiff's Complaint.

SIXTH AFFIRMATIVE DEFENSE

117. Any and all damages alleged by Plaintiff may have been caused by misuse of the product at issue, failure to use the product properly, and/or alteration or negligent use of the product.

SEVENTH AFFIRMATIVE DEFENSE

118. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

119. The occurrences and injuries alleged in Plaintiff's Complaint were caused or contributed to by the negligence, breaches of warranty, or defective products of third parties over whom P&G and sanofi-aventis US had no control and for whom they are not responsible.

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NINTH AFFIRMATIVE DEFENSE

120. Plaintiff's claims may be barred by the negligence/fault of others, and/or by the assumption of risks, if any, inherent in the alleged use of the product at issue by Plaintiff and/or the treating physicians and/or other health care providers. Defendants thus rely on the doctrine of comparative fault with regard to any negligence/fault of Plaintiff and any non-party tortfeasors.

TENTH AFFIRMATIVE DEFENSE

121. If Plaintiff suffered the injuries and damages alleged in the Complaint, such injuries resulted, in whole or in part, from the culpable conduct and negligence of Plaintiff and/or of third parties, not from any negligence or breach of duty by P&G and sanofi-aventis US.

ELEVENTH AFFIRMATIVE DEFENSE

and independent cause which was the proximate and/or producing cause and/or the sole proximate and/or sole cause of the occurrences and injuries alleged. Moreover, the occurrences and injuries were caused by separate and independent events or agencies not reasonably foreseeable. Such separate and independent events or agencies destroy the causal connection, if any, between any alleged breach of legal duty on the part of P&G and sanofi-aventis US and the occurrences and injuries alleged by Plaintiff, and thereby become the immediate and/or sole cause and/or sole proximate cause of such occurrences and injuries, relieving P&G and sanofi-aventis US of liability to Plaintiff or any other parties.

TWELFTH AFFIRMATIVE DEFENSE

123. If Plaintiff suffered the injuries or incurred the expenses alleged, the same may have been caused, in whole or in part, by operation of nature or act of God.

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THIRTEENTH AFFIRMATIVE DEFENSE

124. If Plaintiff suffered the injuries or incurred the expenses alleged, the same may have been caused by an idiosyncratic reaction, without any negligence, defect, or failure on the part of P&G and sanofi-aventis US.

FOURTEENTH AFFIRMATIVE DEFENSE

125. If Plaintiff suffered the injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and unrelated medical, genetic and environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses for which P&G and sanofi-aventis US are not responsible.

FIFTEENTH AFFIRMATIVE DEFENSE

126. The FDA has implemented a comprehensive regulatory scheme governing the safety and efficacy of prescription drugs. The drug at issue in this case (the "product" or "product at issue") was approved by the FDA pursuant to such applicable statutes and regulations and, pursuant to such, could only be used pursuant to the prescription of a licensed prescriber. The labeling for the product at issue was also approved by the FDA and the marketing was conducted in conformity with the FDA's rules and regulations. Actonel was subject to and received pre-market approval by the Food & Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301. To the extent Plaintiff asserts claims based on P&G's and sanofi-aventis US's adherence to and compliance with applicable federal laws, regulations and rule, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

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SIXTEENTH AFFIRMATIVE DEFENSE

127. Plaintiff cannot recover because the product at issue was designed and/or made in accordance with the state of the art at the relevant time.

SEVENTEENTH AFFIRMATIVE DEFENSE

128. P&G and sanofi-aventis US state that the benefits of the product at issue outweigh the risks, if any, which may be attendant to its use.

EIGHTEENTH AFFIRMATIVE DEFENSE

129. Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations.

NINETEENTH AFFIRMATIVE DEFENSE

130. Plaintiff's claims are barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

TWENTIETH AFFIRMATIVE DEFENSE

131. To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

TWENTY-FIRST AFFIRMATIVE DEFENSE

132. To the extent that Plaintiff relies upon any theory of breach of warranty, Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

TWENTY-SECOND AFFIRMATIVE DEFENSE

133. Actonel is a prescription pharmaceutical that was available only upon the prescription of a licensed physician, and persons other than P&G and sanofi-aventis US,

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including Plaintiff's treating physicians and health care personnel and institutions, stood in the position of learned intermediaries between P&G and sanofi-aventis US and Plaintiff. Any claims against P&G and sanofi-aventis US accordingly are barred in whole or in part by the learned intermediary doctrine because P&G's and sanofi-aventis US's only obligation is to warn the Plaintiff's prescribing physician, and that obligation was fulfilled.

TWENTY-THIRD AFFIRMATIVE DEFENSE

134. Plaintiff's claims are barred as a matter of law pursuant to Restatement (Third) of Torts §§ 2, 4, and 6.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

135. Plaintiff's claims relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First Amendment rights to petition the government.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

136. This case is more appropriately brought in a different venue.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

137. To the extent Plaintiff settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, P&G and sanofi-aventis US's liability, if any, should be reduced accordingly.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

138. Plaintiff's claims are barred in whole or in part because Plaintiff has failed to mitigate the alleged damages.

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JURY DEMAND

P&G and sanofi-aventis US hereby demand a trial by jury on all of Plaintiff's claims.

WHEREFORE, Defendants P&G and sanofi-aventis US pray for judgment as follows:

- 1. That Plaintiff take nothing by her Complaint;
- 2. For such other and further relief as the court may deem just and proper.

Dated: July 3, 2008

Respectfully submitted,

James H. Neale (JN6972)

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Of Counsel

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CERTIFICATE OF SERVICE

I certify that this document was served by U.S. Mail on July

, 2008 on the following

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